Section 5 – 510(k) Summary

Prepared: 24 October 2013

510(k) Owner

Trudell Medical International
725 Third Street
London, Ontario N5V 5G4
CANADA

Contact Person: Darryl Fischer
Associate Director, Global Regulatory Affairs
Phone: 1-519-455-7060 ext 2140
Fax: 1-519-455-6329
e-mail: dfischer@trudellmed.com

Device Name

Proprietary: ***Ombra**** Table Top Compressor
Common/Classification: Compressor, air, portable

OCT 2 4 2013

Product Code

BTI

Classification Regulation

868.6250

Predicate Device

510(k) Number	***Trade/Model Name***	***Manufacturer***
K031413	Airial MQ5600	Medquip
K092918	Pari Vios Compressor	Pari

Device Description

The ***Ombra**** Table Top Compressor provides a source of compressed air for use with jet nebulizers. The device is a motor-driven compressor, housed in a plastic case with rubber skids. It operates from 120V/60Hz. It is supplied with several replaceable air filters. The ***Ombra**** Table Top Compressor is intended for adult, child and pediatric patients. The device is non-sterile, prescription-use only, intended for use in hospital, clinic, or home environments.

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Intended Use

The ***Ombra**** Table Top Compressor is designed to deliver compressed air to a jet or pneumatic nebulizer. This compressor may be used with adult, child or pediatric patients. The ***Ombra**** Table Top Compressor is a medical device, and should only be used as directed by your healthcare professional. The intended environments for use include the home, hospitals and clinics.

Technological Characteristic Comparison to Predicate Device(s)

Characteristics	***Ombra**** Table Top Compressor Current 510(k) Application	Airial MQ5600 (Predicate) 510(k) K031413
Power	AC 120V, 60Hz powered	AC 120V, 60Hz powered
Principle of operation	delivers compressed air to a jet or pneumatic nebulizer.	delivers compressed air to a jet or pneumatic nebulizer.
Mechanism of action	motor-driven	motor-driven
Patient Contact	no patient-contacting components	no patient-contacting components
Weight (lbs)	3.35	2.7
Dimensions (LxWxH) (mm)	180x145x105	170x135x88
Sound Level (dB A)	62.5	58.6
Maximum Pressure (psi)	43.1	28.8
Operating Pressure (psi)	19.6	16.4
Free Flow Rate (L/min)	9.13	10.46
Operating Flow (L/min)	4.52	4.09
Voltage (V_{ac})	122	122
Free Flow Current (A)	0.88	0.77
Operating Current (A)	0.93	0.81
Maximum Current (A)	0.87	0.78
Operating Temperature Range	+15°C to +40°C (59°F to 104°F)	+10°C to +40°C (50°F to 104°F)
Operating Humidity Range	15 to 95% (non-condensing)	10 to 95% RH
Storage/ Transport Temperature Range	-20°C to +60°C (-4°F to 140°F)	-20°C to +60°C (-4°F to 140°F)
Storage/Transport Humidity Range	15 to 95% (non-condensing)	10 to 95% (non-condensing)

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Characteristics	***Ombra**** Table Top Compressor Current 510(k) Application	Pari Vios Compressor 510(k) K092918
Maximum Pressure (psi)	43.1	43.7
Operating Pressure (psi)	19.6	19.6

The Ombra* Table Top Compressor maximum and operating pressures are somewhat higher than the Airial MQ5600 (Predicate) 510(k) K031413, but less than or equal to the previously cleared Pari Vios compressor 510(k) K092918. The maximum and operating pressures of the subject device raises no new issues and demonstrates the device is as safe and as effective as other devices in the market.

Relevant differences between the ***Ombra**** Table Top Compressor and the Airial MQ5600 predicate device;

- outer case
- the motor power

Non-Clinical Test Summary

Testing was conducted to characterize the operating parameters of the ***Ombra**** Table Top Compressor to the predicate device.

The ***Ombra**** Table Top Compressor has been tested to determine the maximum emission levels emanating from the device, its ensured severity levels and performance criterion. The device is technically compliant with the requirements of EN 60601-1-2:2007 Electromagnetic Compatibility standard.

The ***Ombra**** Table Top Compressor has been tested to determine its compliance against IEC EN 60601-1:2005 + Corr. 1 (2006) + Corr. 2 (2007). The device is technically compliant with the requirements of the standard.

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Clinical Performance Summary

Not applicable, the determination of substantial equivalence is not based on Clinical Performance Data

Conclusions from Testing

The ***Ombra**** Table Top compressor has been evaluated against the currently marketed (predicates) Airial MQ5600 and Pari Vios for the determination of substantial equivalency. The ***Ombra**** Table Top compressor and the predicate devices share common indications for use, operating characteristics and usage environments. The devices are both single patient use, non-sterile and are available by prescription. The differences in the devices do not add any new type of safety or effectiveness questions. The ***Ombra**** Table Top compressor has been demonstrated to be as safe and as effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 24, 2013

Trudell Medical International
Darryl Fischer, CQM
Associate Director, Global Regulatory Affairs
725 Third Street
LONDON, ONTARIO
CANADA, N5V 5G4

Re: K131881
Trade/Device Name: Ombra* Table Top Compressor
Regulation Number: 21 CFR 868.6250
Regulation Name: Compressor, air, portable
Regulatory Class: Class II
Product Code: BTI
Dated: July 22, 2013
Received: July 26, 2013

Dear Mr. Fischer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

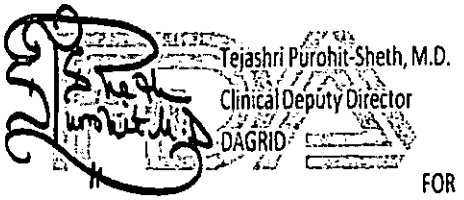
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



FOR

Kwame Ulmer, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K131881

Device Name:

Indications for Use:

The ***Ombra**** Table Top Compressor is designed to deliver compressed air to a jet or pneumatic nebulizer. This compressor may be used with adult, child or pediatric patients. The ***Ombra**** Table Top Compressor is a medical device, and should only be used as directed by your healthcare professional. The intended environments for use include the home, hospitals and clinics.

Prescription Use: ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

K131881 Anya C. Harry -S Digitally signed by Anya C. Harry -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Anya C. Harry -S, 0.9.2342.19200300.100.1.1=0011315590 Date: 2013.10.24 02:36:27 -04'00'

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